1995, 60 FR 15200 (1995), in response to a separate petition from NEMA.[2]

In light of overlapping labeling requirements of the Light Bulb Rule and the Appliance Labeling Rule for incandescent light bulbs (other than incandescent reflector bulbs) and the pending proposed amendments to the labeling requirements for incandescent light bulbs (including incandescent reflector bulbs) under the Appliance Labeling Rule, the Commission has determined that an extension of the comment period is appropriate. Therefore, to allow all interested persons the opportunity to supply the Commission with written data, views and arguments concerning the Commission's review of the Light Bulb Rule, the Commission grants an extension of the comment period to August 7, 1995.

List of Subjects in 16 CFR Part 409

Advertising, Consumer protection, Energy conservation, Household appliances, Labeling, Lamp products, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 95–13361 Filed 5–31–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 186

[Docket No. 80N–0196]

Japan Wax; Affirmation of GRAS Status as an Indirect Human Food Ingredient; Reproposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Reproposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm Japan wax as generally recognized as safe (GRAS) as an indirect human food ingredient for use as a constituent of cotton and cotton fabrics used in dry food packaging. In light of this action, the agency is withdrawing its July 9, 1982 (47 FR 29965), proposal to delete this use of Japan wax from GRAS status as an indirect human food ingredient (hereinafter referred to as the July 1982 proposal). This action results from FDA's review of all available information on Japan wax, including documents located in food additive extension file no. 393 (FAX 393) supporting its history of common use in food contact cotton bags and an acute oral toxicity study on mice that has been obtained since the publication of the July 1982 proposal to delete this use from the GRAS list.

DATES: Written comments by August 15, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has been conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. Under this review, the agency has evaluated the safety of Japan wax, and FDA has reconsidered its July 1982 proposal to remove Japan wax from the GRAS list.

Japan wax (CAS Reg. No. 8001–39–6), also known as Japan tallow or sumac wax, is a pale yellow vegetable tallow, containing glycerides of the C_{19}–C_{23} dibasic acids and a high content of tripalmitin. It is prepared from the mesocarp by hot pressing of immature fruits of the oriental sumac, *Rhus succedanea* (Japan, Taiwan and Indo-China), *R. vernicifera* (Japan), and *R. trichocarpa* (China, Indo-China, India, and Japan).

Japan wax is listed in § 182.70 (21 CFR 182.70) as GRAS for use as a substance migrating to food from cotton and cotton fabrics used in dry food packaging based upon a final rule published in the **Federal Register** of June 10, 1961 (26 FR 5224). This final rule was the original GRAS listing for substances migrating to food from cotton and cotton fabrics used in dry food packaging and included only substances in common use prior to that time. Japan wax was one of the substances identified to FDA, in response to the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the act), by the National Cotton Council of America as being in use prior to 1958 in food contact articles (cotton bags) (Ref. 1). One member of the Council, Seydel-Woolley & Co., had reported using Japan wax for the sizing of cloth used for food bags or similar uses (Ref. 2). Japan wax had been in use in textile finishing for many years (Refs. 3 and 4). Japan wax is also listed in § 73.1(b)(2) (21 CFR 73.1(b)(2)) for use in diluents in color additive mixtures for coloring shell eggs, in § 175.105 (21 CFR 175.105) for use as a component of adhesives, in § 175.350 (d)(3) (21 CFR 175.350 (d)(3)) for use as an optional substance in vinyl acetate/crotonic acid copolymer, and in § 176.170 (a)(5) (21 CFR 176.170 (a)(5)) for use as a component of paper and paperboard in contact with aqueous and fatty foods. This action does not affect these regulated food additive or color additive uses of Japan wax.

The July 1982 proposal stated that insufficient safety data existed to affirm the GRAS status of the ingredient for indirect human food use. The July 1982 proposal also stated that the proposed action would not affect the regulated uses of Japan wax as a food additive and as a color additive diluent. The July 1982 proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

The basis for the July 1982 proposal was the evaluation of the 1975 final report of the Select Committee on GRAS Substances (the Select Committee), composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (LSRO/FASEB). This report was one of a series concerning the health aspects of using GRAS and prior-sanctioned food substances as food ingredients, done by LSRO/FASEB under contract with FDA. FDA requested these reviews of the safety of substances that were listed as GRAS only on the basis of their common use in food prior to 1958. The Select Committee's report, entitled ''Evaluation of the Health Aspects of Japan Wax as a Substance Migrating to Food from Cotton and Cotton Fabrics Used in Dry Food Packaging'' (Ref. 5), included the results of an in vitro mutagenic evaluation of Japan wax

[2] NEMA also notes that the U.S. Department of Energy (''DOE'') has published ''interim final rules'' regarding test procedures for incandescent light bulbs (and for other lamp products covered by the Appliance Labeling Rule). See Interim final rule, 59 FR 49468 (1994). NEMA states that, given the interim final status of the DOE testing rules, an extension of the comment period in the review of the Light Bulb Rule ''would more likely enable the commentators to base their comments and recommendations upon final Department of Energy test procedure regulations.'' The Commission stated in the Statement of Basis and Purpose for the lamp labeling amendments to the Appliance Labeling Rule that it would consider testing performed according to the test procedures mandated by DOE in its final testing rules as meeting the reasonable basis standard required by the Appliance Labeling Rule, 59 FR 25176, 25200 (1994). Therefore, final action by DOE on its testing rules is not necessary for the Commission to conduct the current review of the Light Bulb Rule.

using *Saccharomyces cerevisiae*, strain D4, and *Salmonella typhimurium*, strains TA–1536, TA–1537, and TA–1538, with and without metabolic activation (Ref. 6). In these assays, Japan wax exhibited no mutagenic activity. The Select Committee's report, however, concluded that there were insufficient data upon which to evaluate the safety of Japan wax for use as a substance migrating to food from cotton and cotton fabrics used in dry food packaging. Although FDA proposed to remove this use from the GRAS list, the July 1982 proposal further stated that if information was subsequently obtained to support the safe use of Japan wax in cotton and cotton fabrics for use in dry food packaging, FDA would reconsider the July 1982 proposal.

In the **Federal Register** of August 28, 1991 (56 FR 42668) (hereinafter referred to as the August 1991 notice of intent), FDA published a notice of intent to review all of the proposed rules that the agency had published in the **Federal Register** on or before December 31, 1985, but for which no final rule or notice of withdrawal had been published. The agency then tentatively concluded that 115 of these pre-1986 proposals should be withdrawn, including the proposed deletion of Japan wax from GRAS status, and invited comments on FDA's intent to withdraw these proposals. No comments were received concerning Japan wax.

After due consideration of all comments received in response to the August 1991 notice of intent, FDA announced in the **Federal Register** of December 30, 1991 (56 FR 67440), that it was withdrawing 89 proposed rules that were published in the **Federal Register** on or before December 31, 1985, and was deferring a decision on withdrawal of 26 proposed rules. The agency also announced that it had, on its own initiative, further reviewed its proposal to withdraw the proposed deletion from GRAS status of Japan wax, published in the July 1982 proposal, and had decided to defer the withdrawal of this proposal.

II. Safety

Since the publication of the Select Committee's report, FDA has found evidence that bears on the safe use of Japan wax in the treatment of cotton fabric used for dry food packaging. The agency has received and considered an acute oral toxicity study in which mice were given 15 grams per kilogram body weight doses of Japan wax for 5 days (Ref. 7). No mortality was observed and no adverse effects were noted in this study. The agency has also conducted a review of the scientific literature since the 1975 final report of the Select Committee and has found no information that would cause any safety concerns about this use of Japan wax.

After obtaining the acute oral toxicity study, FDA reexamined the documents in its possession and other evidence supporting the history of common use of Japan wax in cotton fabrics used in dry food packaging. The agency found letters from a textile manufacturer and from the National Cotton Council of America in a food additive extension file (FAX 393), identifying Japan wax as one of the substances being used in the sizing of cloth used for food bags prior to 1958 (Refs. 1 and 2). FAX files contain the administrative record of industry requests for continued use of food ingredients, pending FDA's publication of regulations as required by the 1958 Food Additives Amendment to the act. The requests were made in the period immediately following the passage of the Food Additives Amendment.

As provided for under § 170.30(b) (21 CFR 170.30(b)), FDA has tentatively determined that the history of safe use of Japan wax since before 1958 provides an adequate basis upon which to affirm that the use of Japan wax in cotton and cotton fabrics used in dry food packaging is GRAS. The GRAS status of this use is corroborated by the acute study and by the in vitro mutagenic evaluation. Therefore, in accordance with the provisions of §§ 170.30 and 170.35 (21 CFR 170.35), the agency is proposing to affirm that Japan wax is GRAS for use as a constituent of cotton and cotton fabrics used in dry food packaging, on the basis of its common use in food prior to 1958, corroborated by further evidence of its safety obtained since the Select Committee's evaluation.

III. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not prohibit any current activity, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Environmental Impact

FDA has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Prior Sanctions

The agency is unaware of any prior sanction for the use of this ingredient in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act (21 U.S.C. 342), and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of their right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under part 181 (21 CFR part 181) or affirming it as GRAS under part 184 or 186 (21 CFR part 184 or 186), as appropriate.

VI. Comments

Interested persons may, on or before August 15, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets

Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter to the Commissioner, FDA, from National Cotton Council of America, with attached Sheet V, (3 pp.), January 25, 1960.

2. Letter to John Howard, National Cotton Council of America, from Paul Seydel, Seydel-Woolley & Co., with attached list, March 25, 1960.

3. Sayre, J. E. and C. J. Marsel, CW Report ''The $100 Million Market for Waxes,'' *Chemical Week*, p. 47, September 27, 1952.

4. Warth, A. H., ''Japan wax,'' *The Chemistry and Technology of Waxes*, 2d ed., Reinhold Publishing Corp., pp. 270–274, 1956.

5. ''Evaluation of the Health Aspects of Japan Wax as a Substance Migrating to Food From Cotton and Cotton Fabrics Used in Dry Food Packaging,'' Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1975.

6. Litton Bionetics, Inc., LBI Project No. 2468, Mutagenic Evaluation of Compound, FDA 73–50, MX8001–39–6, Japan Wax, December 24, 1975.

7. Leberco Laboratories, Assay No. 22753, Unpublished Acute Oral Toxicity Test of Japan Wax in Charles River CF–1 Mice, March 8, 1982.

List of Subjects

21 CFR part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR part 186

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, the proposed rule that published in the **Federal Register** of July 9, 1982 (47 FR 29965) is withdrawn; and it is proposed that 21 CFR parts 182 and 186 be amended to read as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§ 182.70 [Amended]

2. Section 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* is amended by removing the entry for ''Japan wax.''

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 186 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. New § 186.1555 is added to subpart B to read as follows:

§ 186.1555 Japan wax.

(a) Japan wax (CAS Reg. No. 8001–39–6), also known as Japan tallow or sumac wax, is a pale yellow vegetable tallow, containing glycerides of the C_{19}–C_{23} dibasic acids and a high content of tripalmitin. It is prepared from the mesocarp by hot pressing of immature fruits of the oriental sumac, *Rhus succedanea* (Japan, Taiwan, and Indo-China), *R. vernicifera* (Japan), and *R. trichocarpa* (China, Indo-China, India, and Japan). Japan wax is soluble in hot alcohol, benzene, and naphtha, and insoluble in water and in cold alcohol.

(b) In accordance with paragraph (b)(1) of this section, the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based on the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: May 16, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–13293 Filed 5–31–95; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MN–28–1–6163; FRL–5213–7]

Approval and Promulgation of Implementation Plans; Minnesota Carbon Monoxide Contingency Measure

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: The USEPA is proposing to approve the carbon monoxide (CO) contingency measure as a revision to the Minnesota State Implementation Plan (SIP) in the Twin-Cities area. This area is designated moderate nonattainment for CO. It includes the Twin Cities of Minneapolis-Saint Paul and the following counties which comprise the CO control area: Anoka, Carver, Chisago, Dakota, Hennepin, Isanti, Ramsey, Scott, Washington, and Wright. The USEPA action is based upon a request that was submitted by the State to satisfy the requirement of section 172(c)(9) of the Clean Air Act as amended in 1990 (CAAA). This section of the CAAA requires States with areas designated moderate or above CO or ozone nonattainment to submit contingency measures by November 15, 1993. These measures must take effect, without further action by the State or the USEPA, if an area fails to make reasonable further progress or to attain by the attainment date. The State submittal meets this requirement, of no further action to implement, because the State legislation that authorizes this measure requires the use of oxygenated gasoline on a year-round basis beginning October 31, 1995, in areas classified as CO control areas. In the State's plan no trigger event is required. Ethanol is expected to be the primary oxygenate in this area and will in large part be used to meet the year-round oxygenate requirement. Thus, in addition to the benefits from the reduction of CO emissions through the use of oxygenated gasoline, the expected use of ethanol in implementing this contingency measure is consistent with the longstanding Federal policy of using renewable fuels for a positive energy impact and the reduction of emissions of greenhouse gases.

DATES: Comments on this SIP revision and on the proposed USEPA rulemaking action must be received by July 3, 1995, to be considered in the development of the USEPA's final rulemaking action.

ADDRESSES: Written comments should be addressed to: William L. MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE–17J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the revision request and USEPA's analysis are available for public inspection during normal business hours at the following addresses: United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard (AE–17J), Chicago, Illinois 60604; and Office of Air and Radiation (OAR), Docket and Information Center (Air Docket (6102) Room M1500, United States Environmental Protection